No. 25-1722

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

IN RE: ENTRESTO (SACUBITRIL/VALSARTAN)

NOVARTIS PHARMACEUTICALS CORPORATION,

Plaintiff-Appellee,

v.

MSN PHARMACEUTICALS, INC.; MSN LABORATORIES PRIVATE LTD.; MSN LIFE SCIENCES PRIVATE LTD.,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Delaware, No. 1:20-md-02930, Hon. Richard G. Andrews

NOVARTIS PHARMACEUTICALS CORPORATION'S NOTICE OF INTENT TO RESPOND, RESPONSE TO IMMEDIATE STAY REQUEST, AND OBJECTION TO EXPEDITION

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MAY 2, 2025

Earlier today, MSN filed an emergency motion under Federal Rule of Appellate Procedure 8 seeking to stay—immediately and for the duration of this appeal—the provision of the district court's April 1, 2025 final judgment ordering a reset of the effective approval date of MSN's ANDA. The district court's final judgment is based on this Court's April 1, 2025 mandate following a unanimous, precedential decision by Judges Lourie, Prost, and Reyna. Because MSN's motion and appeal relate to that panel's January 10, 2025 decision upholding the validity of Novartis's patent, Novartis respectfully suggests that it would be appropriate, under this Court's rules, to assign MSN's motion to that same panel.[1]

Novartis respectfully submits this notice of intent to respond to MSN's motion for a stay pending appeal. Novartis also writes to make clear that MSN does not seek to stay, and thus accepts during the pendency of its appeal, the portion of the district court's post-appeal final judgment that enjoins MSN from commercial marketing and sales of generic versions of Novartis's lifesaving heart-failure treatment ENTRESTO®. Add126-27. Indeed, MSN's motion affirmatively relies on the continuance of the injunction (MSN.Mot.19-20), which is necessary to protect Novartis from the irreparable harm that would ensue were the injunction lifted and

[1] MSN filed identical motions in Appeal Nos. 25-1722 and 25-1723. These appeals should be consolidated, as they result from the same district court order being docketed in both the district court MDL case number and the individual *MSN* case number.

MSN is allowed to maintain its effective FDA approval, and then MSN begins commercial marketing and sales despite Novartis's recognized right to pediatric exclusivity related to Novartis's patent.

Novartis also objects to MSN's assertions of the need for expedition. MSN has already had its day in court, including in this Court. The post-appeal final judgment MSN seeks to partially stay is the culmination of protracted litigation in which the issues were thoroughly aired. Having chosen a litigation strategy and lost after appeal, MSN now seeks for the first time to try a new strategy, one it could have pursued five years ago but did not—as the district court determined in rejecting MSN's motions, a determination well within that court's broad discretion.

1. This case involves Novartis's foundational patent protecting its top-selling drug ENTRESTO®. The patent claims a pharmaceutical composition comprising the active ingredients sacubitril and valsartan in combination, which are expressly recited in the patent's claims by name. *In re Entresto*, 125 F.4th 1090, 1094 (Fed. Cir. 2025) (quoting claims). Following MSN's submission of an ANDA, Novartis sued MSN in 2019 for patent infringement. As the case proceeded, MSN voluntarily chose to proceed to trial on only its invalidity defenses, unconditionally stipulating to infringement and never raising any delisting counterclaim. *Id.* at 1095-100;

D.Ct.Dkt.540.[2] Although MSN's litigation strategy initially led to a district court invalidity judgment, in the appeal that concluded on April 1, 2025, this Court upheld the validity of Novartis's patent. *Entresto*, 125 F.4th at 1097-100.

This Court expressly based its decision on "[t]he invention of the '659 patent, as construed by the district court." *Id.* Affirmatively relying on the district court's "plain and ordinary meaning" construction, the Court rejected MSN's written-description invalidity challenge and arguments about what the claims "'*cover*'" for "conflat[ing] the distinct issues of patentability and infringement." *Id.* The Court thus did not change the claim construction or the claims' scope, which no party had appealed. *Id.*, Oral.Arg.Audio.20:45 (MSN's counsel: "no one has asked to overturn the claim construction"). After ruling for Novartis on the merits of validity, this Court granted Novartis's motion for an injunction pending appeal to prevent MSN from launching its generic versions of ENTRESTO® during Novartis's earned pediatric exclusivity period, which extends until July 16, 2025. *Entresto*, ECF Nos. 65, 73, 119, 127.

When MSN sought en banc reconsideration of this Court's injunction, this Court denied MSN's request for an immediate administrative stay. *Id.*, ECF Nos. 129, 131. MSN also sought panel and/or en banc rehearing on the merits,

[2] D.Ct.Dkt._ cites are to the docket in *In re Entresto (Sacubitril/Valsartan) Patent Litigation*, No. 1:20-md-02930-RGA (D. Del.).

taking the full 30 days permitted under the rules to file its petition. *Id.*, ECF No. 136. In its requests, MSN argued, among other things, that further review was warranted because the Court had purportedly *sua sponte* changed the scope of Novartis's patent claims such that Novartis's patent should be delisted. *Id.*, ECF Nos. 129 at 14-17; 136 at 6-7, 16-18. In opposing, Novartis explained that not only did this Court not alter the claims' scope, but MSN's delisting arguments overlook that the parties agree ENTRESTO® includes a combination of valsartan and sacubitril, the invention claimed and the active ingredients expressly recited in Novartis's patent, making this case nothing like *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, LLC*, 124 F.4th 898, 912 (Fed. Cir. 2024). *Id.*, ECF No. 153 at 16-17; *see* MSN.Mot.5 (conceding "Entresto® contains valsartan and sacubitril"). This Court denied reconsideration of the injunction and denied rehearing of the merits. *Id.*, ECF No. 157. MSN then submitted a letter asking this Court to delay issuing the mandate until expiration of the 7-day period prescribed by Federal Rule of Appellate Procedure 41. *Id.*, ECF No. 158. This Court continued its injunction until issuance of the mandate.

2. On April 1, 2025, the same day this Court's mandate issued, the district court entered final judgment implementing that mandate and continuing the injunction against MSN's commercial marketing and sales. Add125-27. The judgment included the statutorily required order under 35 U.S.C. § 271(e)(4)(A) that

the effective date of any approval of MSN's ANDA shall be no earlier than July 16, 2025, after expiration of the pediatric exclusivity period related to Novartis's patent. Add126-27; *In re Omeprazole Pat. Litig.*, 536 F.3d 1361, 1368-69 (Fed. Cir. 2008). The district court ordered that its injunction would continue "until FDA resets the effective approval date of MSN's ANDA." Add126-27.

MSN immediately moved to vacate, amend, or re-open that final judgment under Federal Rules of Civil Procedure 59 and 60. MSN again argued that this Court's decision had changed the claims' scope, which MSN believed in light of *Teva* warranted raising a never-before-asserted delisting counterclaim and reopening MSN's prior unconditional stipulation of noninfringement. The district court rejected these requests for multiple reasons: the court found "no intervening change in the facts or the controlling law" because the decision of "[t]he Federal Circuit does not change the claim construction"; MSN's request to re-open infringement despite its prior stipulation was "meritless"; and MSN's delisting request was based on "pretty close to a frivolous argument" and was "too late," given MSN's "not raising the delisting argument during five years of litigation until a couple months ago." Add168 (delisting "claim has always been there" but "just wasn't pursued"; was "never advanced before"; "was not even in the consideration of anything in the case"); Add165 (distinguishing *Teva*, where the patent claimed a device but not the active ingredient, and so "was a very different kind of case, very different set of facts

than what we have here"). Indeed, FDA recognizes that sacubitril and valsartan are the "active ingredient[s]" in Entresto. D.Ct.Dkt.1856-2. The active ingredients are in the form of a complex as depicted in the product labeling, but FDA recognizes the complex contains two active ingredients, sacubitril and valsartan.

After denying MSN's motions, the district court granted MSN a 72-hour stay only of the portion of its judgment resetting the effective date of MSN's ANDA approval, which was the only stay pending appeal that MSN requested. Add169. The district court relied on MSN's representation that, because MSN would still be enjoined by the rest of the district court's judgment, there would be no prejudice to Novartis. Add169 (MSN's counsel explaining, "We're enjoined. We don't see any prejudice or harm to Novartis.").

3. Given this history, the continuance of the district court's injunction is critical, both while the parties brief MSN's stay motion and throughout this appeal. MSN has consistently made clear its intent to commercially launch in any window of time without a legal restriction. D.Ct.Dkt.1747 at 5 (MSN representing that it "currently has in the United States finished drug product that it is ready to sell to U.S. healthcare providers"). Yet it is undisputed that any such launch would destroy the status quo, which is that MSN's generic products are not and never have been on the market. Until the FDA effectuates a reset of MSN's ANDA, the district court's

injunction is the only thing protecting Novartis's patent rights and associated regulatory exclusivity.[3]

As for the FDA reset, MSN has no claim of cognizable harm: because of Novartis's valid patent and associated regulatory rights here, MSN's ANDA should never have been granted final approval before July 16, 2025. The district court's post-appeal final judgment merely restores Novartis and MSN to the same positions they should have been in all along, absent the district court's now-reversed invalidity judgment. Nor does MSN have any support for its speculation that it could be irreparably harmed by having its approval delayed beyond July 16, 2025, if required to comply with applicable FDA procedures. MSN.Mot.18-19.

4. Finally, Novartis opposes MSN's request that Novartis respond to MSN's motion stay motion "on an expedited basis" and for "expedited merits briefing by the parties for any issue or on any schedule this Court identifies." MSN.Mot.2. MSN fails to propose any schedule, as the Court's rules require. Fed. Cir. R. 27(c). And any "emergency" here is one of MSN's making. When this Court's decision

[3] The U.S. District Court for the District of New Jersey has also granted Novartis a preliminary injunction based on Novartis's non-patent, trade dress rights, which MSN's generic products were found likely to infringe. Order, *Novartis AG v. Novadoz Pharms. LLC*, No. 2:25-cv-00849 (D.N.J. Mar. 17, 2025), Dkt. 33. MSN rightly does not argue that the trade dress injunction provides any basis for disturbing the final judgment injunction here. The trade dress injunction protects different legal rights. MSN also has a pending motion to stay that preliminary injunction, and the New Jersey district court is currently entertaining reconsideration of its injunction. *Id.*, Dkt. 37, Dkt. 43.

issued in January 2025, Novartis asked this Court to expedite the mandate to allow entry of the district court's judgment, proposing a process that would have allowed MSN to seek rehearing in parallel with any remand proceedings. *Entresto*, ECF No. 110. MSN opposed and then repeatedly acted without any haste in having this case returned to the district court. *Id.*, ECF Nos. 111, 112, 158. And as the district court rightly noted, MSN's delisting arguments have been available to it since this case's inception, yet MSN sat on its rights for five years. Add168.

Under these circumstances, MSN is free to self-expedite its stay and appeal briefing but cannot justify requiring this Court and Novartis to act on an expedited basis. Novartis should thus be given a reasonable opportunity to respond to MSN's stay motion, which asks for different relief than MSN's counsel previously told Novartis MSN would seek. And Novartis should be allowed at least 28 days after MSN's opening brief to prepare its merits response brief, which is less time than MSN afforded itself to file its rehearing petition in the prior appeal.

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As MSN's motion makes clear, the parties agree that the district court's injunction remains in place, including for the duration of this appeal. Novartis intends to respond to the remainder of MSN's stay motion within the 10 days provided by Federal Rule of Appellate Procedure 27(a)(3)(A) absent further order from the Court.

Dated: May 2, 2025

Respectfully submitted,

/s/ Deanne E. Maynard

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CERTIFICATE OF INTEREST

Counsel for Novartis Pharmaceuticals Corporation certify under Federal Circuit Rule 47.4 that the following information is accurate and complete to the best of their knowledge:

1. **Represented Entities**. Provide the full names of all entities represented by undersigned counsel in this case.

Novartis Pharmaceuticals Corporation

2. **Real Parties in Interest.** Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities.

None.

3. **Parent Corporations and Stockholders.** Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities.

Novartis AG

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court.

McCARTER & ENGLISH, LLP: Daniel M. Silver, Alexandra M. Joyce, Maliheh Zare

SCHRADER COMPANION DUFF & LAW PLLC: Sandra K. Law, James F. Companion

VENABLE LLP: Erin Belfield, Shannon K. Clark, Laura K. Fishwick, Susanne L. Flanders, Whitney M. Howard, Christopher E. Loh, Gregory J. Manas, Carrie S. Park, Melinda R. Roberts, Jared L. Stringham

5. **Related Cases.** Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes, see separately filed notice.

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees).

Not applicable.

Dated: May 2, 2025

/s/ Deanne E. Maynard
Deanne E. Maynard

CERTIFICATE OF COMPLIANCE

The foregoing filing complies with the relevant type-volume limitations and typeface and type style requirements of the Federal Rules of Appellate Procedure and Federal Circuit Rules because the filing has been prepared using a proportionally spaced typeface in 14-point Times New Roman font using Microsoft Word and includes 1,935 words, excluding the parts of the filing exempted by the Rules.

Dated: May 2, 2025

/s/ Deanne E. Maynard
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